Remarks

Claims 11-14 stand rejected. Claims 12-14 are objected to as based on a rejected base claim. Claims 1-10 and 23 are allowed. The status of claim 24 was not provided in the office action, but it was not rejected.

Claim 11 is amended here to incorporate the limitation of claim 12. Claim 12 is cancelled. Neither amendment introduces new matter to the application.

Examiner Interview of October 30, 2007

Following an examiner-initiated interview, the undersigned attorney left a voice-mail message for Examiner Canella on October 30, 2007. The undersigned attorney agreed to incorporate the recitation of claim 12 in claim 11 by an examiner's amendment. The current office action does not acknowledge either the interview or the voice-mail message. The same amendment is made in this submission.

The Rejections of Claim 11 Under 35 U.S.C. § 103(a)

Claim 11 is rejected as obvious over two combinationS of references:

- Morris, Sidransky, Shaag, and NEB catalog
- Davies, Sidransky, Shaag, and NEB catalog.

Applicants have amended claim 11 to recite that the test sample is a thyroid sample. The prior art did not teach that the T1796A mutation occurred or was prevalent in thyroid cancers. Thus neither combination of references renders the subject matter of amended claim 11 obvious, because neither combination of references teaches all elements of the claimed subject matter.

Withdrawal of the rejections is respectfully requested in view of the amendment of claim 11.

The Rejection of Claims 11-14 Under 35 U.S.C. §112, first paragraph

Claims 11-14 are rejected as not fully enabled. While acknowledging enablement of the portion of the claim that detects one fewer fragment of TspRI restriction digests, the Patent Office denies enablement of the portion of the claim that detects one additional fragment. This rejection is respectfully traversed.

If the only type of BRAF gene that is present in the sample contains the T1796A mutation, then one would see a loss of a fragment. This would occur if the patient from whom the sample was obtained were homozygous for the mutation or hemizygous, *i.e.,* contained no wild type copy. However, if the patient were heterozygous, containing one T1796A mutant BRAF gene and one wild-type BRAF gene, then one would see an additional fragment. The additional fragment would derive from the mutant gene, while the two "original" fragments would still be present from the wild-type gene. This is described in the specification at paragraph [18]:

> If a restriction enzyme cleavage and/or recognition site is destroyed by a transversion mutation, then two fragments of a wild-type allele will be joined. Thus from the mutant allele, there will be one fewer fragments. If both alleles in the sample are mutant, then there will be one fewer fragment in the sample. If only one allele is mutant and one allele remains wild-type, then the sample will have an additional fragment (the fused fragments) relative to a wild-type sample.

One of skill in the art would be able to practice the claimed method without undue experimentation and with a reasonable expectation of success based on the teaching of the specification. Withdrawal of this rejection is respectfully requested.

Respectfully submitted,

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